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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/048,071	10/23/2002	Michael E. O'Donnell	22221/1023	1435

7590 07/18/2007

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EXAMINER	
BASKAR, PADMAVATHI	
ART UNIT	**PAPER NUMBER**
1645	

MAIL DATE	DELIVERY MODE
07/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/048,071	O'DONNELL ET AL.	
	Examiner	Art Unit	
	Padmavathi v. Baskar	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,36-38,55-57 and 92-94* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *37, 38 and 92-93* is/are allowed.

6)☒ Claim(s) *1,36,55-57 and 94* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/20/07 has been entered.

Status of claims

2. Claims 2-35, 39-54 and 58-91 are canceled.

Claims 1, 36 and 37 have been amended.

New claims 92-94 have been added.

Claims 1, 36-38, 55-57, and 92-94 are pending and are under examination.

Claim Rejections - 35 USC 101

3. 35 U.S.C. 101 reads as Follows

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

4. Claims 57 and 94 are rejected because as written, do not sufficiently distinguish over cells that exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed product and the product nature.

The product "a host cell" as claimed, has the same characteristics as that found in nature because "a host cell comprising ---- ." can be obtained from any source such as human body cells because infected cells in a human body read on the claims because these cells comprise DNA in a recombinant form (see details in Para # 14 , Bodnar et al , J Clin Microbiol. 1996, and Snyder et al Molecular Genetics of Bacteria, American Society for Microbiology 1997).

The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "isolated" as taught by page [117] of specification. See MPEP 2105.

Claim Rejections - 35 USC § 112, second paragraph

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1, 37, 55-57are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim as written is unclear because what else the DNA molecule comprise in addition that it encodes the amino acid sequence "comprising" SEQ ID NO:27 is unknown. It is suggest that the rejection can be obviated by amending the claim to recite for example: " An isolated DNA molecule that encodes the amino acid sequence , SEQ ID NO:27"

Claims 1 and 55-57are rejected because claim 1 is confusing as it is unclear how one DNA molecule from Staphylococcus and Streptococcus can be the hybridizing molecule that has all of the parameters required and still be from both Staphylococcus and Streptococcus

Claim Rejections - 35 USC 112, first paragraph

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1and 55-57 are rejected under 35 USC 112, first paragraph, as lacking an adequate written description in the specification.

Claims are drawn to an isolated DNA molecule from a Gram positive bacterium selected from the group of Staphylococcus; and Streptococcus, the isolated DNA molecule comprising a coding region from a dnaN gene, wherein the coding region encodes a polypeptide that has activity as a beta clamp and is capable functionally interacting with a polymerase during DNA polymerization, and wherein the isolated DNA molecule hybridizes to the complement of SEQ ID NO: 27 under conditions comprising a hybridization buffer comprising 0.9M SSC at 37°C and washing in 0.2X SSC at 42°C and expression system. Host cell expressing said nucleic acid.

It is conventional and well known in the art, as taught by US Patent No. 5,912,143 that the term complementary refers to the natural binding of polynucleotides under permissive salt and temperature conditions and specifically teaches that complementarity between two single-stranded molecules may be "partial" or it may be "complete" (col 5, lines 19-32), as taught in the instant specification. When given the broadest reasonable interpretation, the claims are clearly intended to encompass a variety of species including full-length cDNAs, genes and protein coding regions. Clearly, it would be expected that a substantial number of the complementary polynucleotides encompassed by the claims **would not** share either structural or functional properties with polynucleotides that encode SEQ ID NO:28 or encode

proteins that share either structural or functional properties with SEQ ID NO:28

As drawn to DNA arts, the findings in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997) and Enzo Biochem, Inc. V. Gen-Probe Inc. are relevant to the instant claims. The Federal Circuit addressed the application of the written description requirement to DNA-related inventions in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). The court stated that "[a] written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." Id. At 1567, 43 USPQ2d at 1405. The court also stated that a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA" without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is Id. At 1568, 43 USPQ2d at 1406. The court concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id.

Finally, the court addressed the manner by which a genus of cDNAs might be described. "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." Id.

The Federal Circuit has recently clarified that a DNA molecule can be adequately described without disclosing its complete structure. See Enzo Biochem, Inc. V. Gen-Probe Inc., 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002). The Enzo court adopted the standard that "the written description requirement can be met by 'show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics ....i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. " Id. At 1324, 63 USPQ2d at 1613 (emphasis omitted, bracketed material in original).

The inventions at issue in Lilly and Enzo were DNA constructs per se, the holdings of those cases are also applicable to claims such as those at issue here. A disclosure that does not adequately describe a nucleic acid variant itself logically cannot adequately describe expression system and host cells that comprise said variant nucleic acid .

Thus, the instant specification may provide an adequate written description of an isolated DNA molecule from a Gram positive bacterium selected from the group of Staphylococcus; and Streptococcus, the isolated DNA molecule comprising a coding region from a dnaN gene, wherein the coding region encodes a polypeptide that has activity as a beta clamp and is capable functionally interacting with a polymerase during DNA polymerization, and wherein the isolated DNA molecule hybridizes to the complement of SEQ ID NO: 27 under conditions comprising a hybridization buffer comprising 0.9M SSC at 37°C and washing in 0.2X SSC at 42°C per Lilly by structurally describing a representative number of variant DNA molecule, "structural features common to the members of the genus, which features constitute a substantial portion of the genus." Alternatively, per Enzo, the specification can show that the claimed invention is complete "by disclosure of sufficiently detailed, relevant identifying characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics."

In this case, the specification does not describe variant DNA molecules in a manner that satisfies either the Lilly or Enzo standards. The specification does not provide the complete structure of nor does the specification provide any partial structure of variant DNA molecules nor any physical or chemical characteristics variant DNA molecules nor any functional characteristics coupled with a known or disclosed correlation between structure and function other than SEQ ID NO: 27 . Although the specification discloses a single isolated DNA molecule set forth as SEQ.ID.NO:27 that encodes the amino acid sequence, SEQ.ID.NO:28 from S.pyogenes that would satisfy the standard set out in Enzo. The specification also fails to describe an variant DNA molecules of SEQ ID NO:27 by the test set out in Lilly. The specification describes only a single isolated DNA molecule comprising the nucleotide sequence SEQ.ID.NO:27 Therefore, it necessarily fails to describe a "representative number" of such species. In addition, the specification also does not describe "structural features common to the members of the genus, which features constitute a substantial portion of the genus."

Thus, the specification does not provide an adequate written description of variant DNA molecules of SEQ ID NO:27 that is required to practice the claimed invention. Since the specification fails to adequately describe variant DNA molecules of SEQ ID NO:27 it also fails to adequately describe expression system and host cell comprising said variant DNA molecules of SEQ ID NO:27.

Claims 1 and 55-57 do not comply with 35 USC 112, first paragraph because it is not supported by an adequate written description in the specification.

9. Claims 1 and 55-57 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated DNA molecule from a Gram positive bacterium , Streptococcus pyogenes, the isolated DNA molecule comprising the nucleic acid SEQ ID NO: 27 that encodes dnaN polypeptide set forth as SEQ.ID.NO:28 that has activity as a beta clamp and is capable of functionally interacting with a polymerase during DNA polymerization, and wherein the isolated DNA molecule hybridizes to the full complement of SEQ ID NO: 27, expression system and host cell expressing said

nucleic acid does not reasonably provide enablement for an isolated DNA molecule from a Gram positive bacterium selected from the group of Staphylococcus; and Streptococcus, the isolated DNA molecule comprising a coding region from a dnaN gene, wherein the coding region encodes a polypeptide that has activity as a beta clamp and is capable functionally interacting with a polymerase during DNA polymerization, and wherein the isolated DNA molecule hybridizes to the complement of SEQ ID NO: 27 under conditions comprising a hybridization buffer comprising 0.9M SSC at 37°C and washing in 0.2X SSC at 42°C and expression system. Host cell expressing said nucleic acid. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The instant claims are evaluated for scope of enablement based on the Wands analysis. Many of the factors regarding undue experimentation have been summarized in *In re Wands*, 858 F.2d 731,8 USPQ2d 1400 (Fed.Circ.1988) as follows:

(1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

It is noted that given the unlimited a definition for the term "complementary", wherein the specification does not specifically teach what complementary" means it is assumed for examination purposes that the term complementary has the art recognized meaning of the term wherein complementary refers to the natural binding of polynucleotides under permissive salt and temperature conditions which includes both partial and complete complementarity (see US Patent No. 5,912,143, col 5, lines 19-32), wherein complementarity of even a single nucleic acid residue is a partial complement and meets the limitations of the claims.

As drawn to the unlimited complementary polynucleotides with the hybridization conditions which are moderate conditions that would be expected to lead to the hybridization of a DNA molecules that don't have the structure required for the claimed functions .Again the term complementary is not defined by either the claims or the specification as originally filed, thus complementary polynucleotides include those that have partial or complete complementarity to SEQ ID NO:27 and in particular read on those with only two or three nucleic acid residues that are complementary to those found in SEQ ID NO:27. Thus, complementary polynucleotides include not only the complement, which is completely complementary to the coding sequence of SEQ ID NO:27, but also includes a substantial number of species which lack significant complementarity to SEQ ID NO:27.

The specification teaches dnaN gene of Streptococcus pyogenes encoding the Beta subunit. The dnaN gene has a nucleotide sequence which corresponds to SEQ. ID. No. 27 and said DNA encodes the amino acid sequence SEQ.ID.NO:28. However, the specification contemplates that an isolated DNA molecule from a Gram positive bacterium selected from the group of Staphylococcus; and Streptococcus, the isolated DNA molecule comprising a coding region from a dnaN gene, wherein the coding region encodes a polypeptide that has activity as a beta clamp and is capable of functionally interacting with a polymerase during DNA polymerization, and wherein the isolated DNA molecule hybridizes to the full complement of SEQ ID NO: 27.

One cannot extrapolate the teaching of the specification to the scope of the claims because the specification does not teach the amino acid residues critical to the claimed activity as a beta clamp and functionally interacting with a polymerase during DNA polymerization . Further , one could not predictably distinguish between those molecules that will function as claimed and those that will not, given that the specification fails to teach the critical amino acids required for beta clamp activity in Staphylococcus; and Streptococcus, Clearly, it would be expected by one of ordinary skill in the art that a substantial number of the hybridizing or complementary polynucleotides encompassed by the claims would not encode proteins that share either structural or functional properties with SEQ ID NO:27 or polynucleotide sequences encoding the protein SEQ.ID.NO:28 and it would not be expected that any of the polynucleotides without, substantial complementarity to the polynucleotide encoding SEQ ID NO:27, could function as contemplated because protein chemistry is probably one of the most unpredictable areas of biotechnology and the art teaches that the significance of any particular amino acid and sequences for different aspects of biological activity can not be predicted a priori and must be determined empirically on a case by case basis (Rudinger et al, in "PEPTIDE HORMONES", edited by Parsons, J.A., University Park Press, June 1976, page 6). The art specifically teaches that even a single amino acid change in a protein leads to unpredictable changes in the biological activity of the protein. For example, replacement of a single lysine residue at position 118 of the acidic fibroblast growth factor by glutamic acid led to a substantial loss of heparin binding, receptor binding, and biological activity of the protein (Burgess et al., The Journal of Cell Biology, 111:2129-2138, 1990). In transforming growth factor alpha, replacement of aspartic acid at position 47 with alanine, or asparagine did not affect biological activity while replacement with serine or glutamic acid sharply reduced the biologic activity of the mitogen (Lazar et al., Molecular and Cellular Biology, 8(3):1247-1252, 1988). These references demonstrate that even a single amino acid substitution or what appears to be an inconsequential chemical modification, will often dramatically affect the biological activity of a protein. Proteins with replacement of a single amino acid residues may lead to both structural and functional changes in biological activity and immunological recognition. For example, Jobling et al. (Mol. Microbiol., 1991, 5(7):1755-67 teaches a panel of single amino acid substitutions by oligonucleotide directed mutagenesis in proteins and they differ in native

conformation, binding and toxicity, thus exemplifying the importance of structural components to biological function. Further, the specification does not provide either guidance on or exemplification of how to use the multitude of polynucleotides encompassed by the claims that do not encode proteins that share either structural or functional properties with SEQ ID NO:27. In view of the above, one of ordinary skill in the art would be forced into undue experimentation to practice the claimed invention.

The specification provides insufficient guidance with regard to these issues drawn to claims 1 and 55-57 and provides no working examples in such a way as to reasonably convey to one of skilled in the relevant art can reasonably make use of the claimed invention. In view of the above, one of ordinary skill in the art would be forced into undue experimentation to practice the claimed invention.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

11. Claim 1 is rejected under 35 U.S.C 102 (b) as anticipated by Pestova et al Mol. Microbiol. 21 (4), 853-862 (1996)or Cheng etal Mol. Microbiol. 23 (4), 683-692 (1997) .

Claim 1 is discussed and viewed in Para # 6.

The prior art as shown below discloses Streptococcus pneumoniae nucleic acid molecule ACCESSION AF000658 which would be expected to hybridizes to complement claimed nucleic acid molecule, SEQ.ID.NO:27 as shown below. Given the high level of homology of the prior art reference, it appears that the prior art sequence encode a polypeptide that has activity as a beta clamp and is capable of functionally interacting with a polymerase during dna polymerization. Since the Office does not have the facilities for examining and comparing applicants DNA with the prior art DNA, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594. The prior art anticipated the claimed invention.

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ACCESSION   AF000658
VERSION     AF000658.1  GI:2109442
KEYWORDS    .
SOURCE      Streptococcus pneumoniae
  ORGANISM  Streptococcus pneumoniae
            Bacteria; Firmicutes; Lactobacillales; Streptococcaceae;
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            Streptococcus.
REFERENCE   1  (bases 1 to 511)
  AUTHORS   Pestova,E.V., Havarstein,L.S. and Morrison,D.A.
  TITLE     Regulation of competence for genetic transformation in
            Streptococcus pneumoniae by an auto-induced peptide pheromone and a
            two-component regulatory system
  JOURNAL   Mol. Microbiol. 21 (4), 853-862 (1996)
  MEDLINE   97032150
   PUBMED   8878046
REFERENCE   2  (bases 1 to 643)
  AUTHORS   Cheng,Q., Campbell,E.A., Naughton,A.M., Johnson,S. and Masure,H.R.
  TITLE     The com locus controls genetic transformation in Streptococcus
            pneumoniae
  JOURNAL   Mol. Microbiol. 23 (4), 683-692 (1997)
  MEDLINE   97206147
   PUBMED   9157240
REFERENCE   3  (bases 1 to 6098)
  AUTHORS   Gasc,A.A.
  TITLE     Direct Submission
  JOURNAL   Submitted (22-APR-1997) Lmgm, CNRS, Route De Narbonne, Toulouse, 31
            31062, France
  Query Match             53.2%;  Score 603.4;  DB 1;  Length 6098;
  Best Local Similarity   70.8%;  Pred. No. 3.2e-101;
  Matches  802;  Conservative    0;  Mismatches  331;  Indels    0;  Gaps    0;

Qy          1 ATGATTCAATTTTCAATTAATCGCACATTATTTATTCATGCTTTAAATACAACTAAACGT 60
              |||||||| ||||||||||||   |  |||||| | || || |||||||  |||||  |
Db       4507 ATGATTCATTTTTCAATTAATAAAAATTTATTTCTACAAGCATTAAATATTACTAAGAGA 4566

Qy         61 GCTATTAGCACTAAAAATGCCATTCCTATTCTTTCATCAATAAAAATTGAAGTCACTTCT 120
              ||||||||  |||||||||||||||||||| | ||| |  | ||||||||  || ||
Db       4567 GCTATTAGTTCTAAAAATGCCATTCCTATTTTATCAACTGTCAAAATTGACGTGACCAAC 4626

Qy        121 ACAGGAGTAACTTTAACAGGGTCTAACGGTCAAATATCAATTGAAAACACTATTCCTGTA 180
                ||| || |||||||  || || || |||||||| ||||||||||   |||| ||  |
Db       4627 GAAGGTGTTACTTTAATTGGTTCAAATGGTCAAATTTCAATTGAAAATTTTATTTCTCAA 4686

Qy        181 AGTAATGAAAATGCTGGTTTGCTAATTACCTCTCCAGGAGCTATTTTATTAGAAGCTAGT 240
              |  |||||| |||||||||| ||||||| |||  |||  | ||  |  | ||||||  |
Db       4687 AAAAATGAAGATGCTGGTTTGTTAATTACTTCTTTAGGTTCGATCCTTCTTGAAGCTTCT 4746

Qy        241 TTTTTTATTAATATTATTTCAAGTTTGCCAGATATTAGTATAAATGTTAAAGAAATTGAA 300
              || ||||| ||| |  | || ||||| || ||| | | | |  || ||||||||||||||
Db       4747 TTCTTTATCAATGTAGTATCTAGTTTACCTGATGTAACTCTTGATTTTAAAGAAATTGAA 4806

Qy        301 CAACACCAAGTTGTTTTAACCAGTGGTAAATCAGAGATTACCTTAAAAGGAAAAGATGTT 360
              ||| | ||| ||||||||||||||||| |||||||| |||||| ||||||||||||||
Db       4807 CAAAATCAAATTGTTTTAACCAGTGGCAAATCAGAAATTACCCTAAAAGGAAAAGATAGC 4866

Qy        361 GACCAGTATCCTCGTCTACAAGAAGTATCAACAGAAAATCCTTTGATTTTAAAAACAAAA 420
              || || ||||| ||  | |||||| | ||| ||   | |||||| ||  |  ||||||||
Db       4867 GAACAATATCCACGAATCCAAGAAATTTCAGCAAGCACTCCTTTAATACTTGAAACAAAA 4926

Qy        421 TTATTGAAGTCTATTATTGCTGAAACAGCTTTTGCAGCCAGTTTACAAGAAAGTCGTCCT 480
              ||| | |||   |||||| |||||||||| ||||| || |||  |||||| ||||||||
Db       4927 TTACTCAAGAAAATTATTAATGAAACAGCCTTTGCTGCAAGTACACAAGAGAGTCGTCCG 4986

Qy        481 ATTTTAACAGGAGTTCATATTGTATTAAGTAATCATAAAGATTTTAAAGCAGTAGCGACT 540
              |||||||||||  || ||  | ||||| ||| | || ||||| || ||| |||| || ||
Db       4987 ATTTTAACAGGTGTCCACTTCGTATTGAGTCAACACAAAGAGTTAAAAACAGTTGCAACA 5046

Qy        541 GACTCTCATCGTATGAGCCAACGTTTAATCACTTTGGACAATACTTCAGCAGATTTGATG 600
              ||||||||||  | |||||      | | ||| | || || | |   |  |||||
Db       5047 GACTCTCATCGCCTAAGCCAGAAAAAATTAACTCTTGAAAAAAATAGTGATGATTTTGAT 5106

Qy        601 GTAGTTCTTCCAAGTAAATCTTTGAGAGAATTTTCAGCAGTATTTACAGATGATATTGAG 660
              || ||  |||| ||    ||| |  | |||||||||| |||||||||||||||| ||
Db       5107 GTCGTAATTCCTAGCCGTTCTCTACGCGAATTTTCAGCGGTATTTACAGATGATATCGAA 5166
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Qy        661 ACCGTTGAGGTATTTTTCTCACCAAGCCAAATCTTGTTCAGAAGTGAACACATTTCTTTT 720
              || || ||| | || ||  |    | ||||||| | || ||||| ||| | |||   ||
Db       5167 ACTGTAGAGATTTTCTTTGCCAATAACCAAATCCTCTTTAGAAGCGAAAATATTAGCTTC 5226

Qy        721 TATACACGCCTCTTAGAAGGAAATTATCCCGATACAGACCGTTTATTAATGACAGAATTT 780
              ||||| || ||| |||||||||| ||||| |||||||| || ||  |    ||||| |||
Db       5227 TATACTCGTCTCCTAGAAGGAAACTATCCTGATACAGATCGCTTGATTCCAACAGACTTT 5286

Qy        781 GAGACGGAGGTTGTTTTCAATACCCAATCCCTTCGCCACGCTATGGAACGTGCCTTCTTG 840
               | ||     ||  ||| |||     |  | | |||||  | ||||| ||||||    |
Db       5287 AACACTACTATTACTTTTAATGTGGTAAACTTACGCCAGTCAATGGAGCGTGCCCGTCTT 5346

Qy        841 ATTTCTAATGCTACTCAAAATGGTACTGTTAAGCTTGAGATTACTCAAAATCATATTTCA 900
               | || | ||| |||||||||||||||| || ||||| ||||   |      | ||
Db       5347 TTATCAAGTGCGACTCAAAATGGTACTGTGAAACTTGAAATTAAGGATGGGGTTGTTAGC 5406

Qy        901 GCTCATGTTAACTCACCTGAGGTTGGTAAGGTAAACGAGGATTTAGATATTGTTAGTCAG 960
              || |||||| |||| || || |||||||| |||||||| ||  | |||| || |
Db       5407 GCCCATGTTCACTCTCCAGAAGTTGGTAAAGTAAACGAAGAAATCGATACTGATCAGGTT 5466

Qy        961 TCTGGTAGTGATTTAACTATCAGCTTCAATCCAACTTACCTTATTGAGTCTTTAAAAGCT 1020
               |||||   ||||| || || || ||||| ||||||||| | ||||| ||| | ||||||
Db       5467 ACTGGTGAAGATTTGACCATTAGTTTCAACCCAACTTACTTGATTGATTCTCTTAAAGCT 5526

Qy       1021 ATTAAAAGTGAAACAGTAAAAATTCATTTCTTATCACCAGTTCGACCATTCACCCTAACA 1080
               | || || |||| || |  |||   ||  | ||| | ||||| ||||| || ||
Db       5527 TTAAATAGCGAAAAGGTGACCATTAGCTTTATCTCAGCTGTTCGTCCATTTACTCTTGTG 5586

Qy       1081 CCAGGCGATGAGGAAGAAAGTTTTATCCAATTAATTACACCAGTACGAACAAA 1133
              ||||  |||   || |||   || || ||  | ||||||||||| || |||||
Db       5587 CCAGCAGATACTGACGAAGACTTCATGCAGCTCATTACACCAGTTCGTACAAA 5639
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12. Claims 1 and 36 are rejected under 35 U.S.C 102 (a) as anticipated by Ueyama et al WO9842845-A1.

Claim 1 is discussed and viewed in Para # 6.

Ueyama et al disclose an isolated DNA from Streptococcus pyogenes as shown below which would be expected to hybridizes to complement nucleic acid SEQ.ID.NO:27. Given the high level of homology of the prior art reference, it appears that the prior art sequence encode a polypeptide that has activity as a beta clamp and is capable of functionally interacting with a polymerase during DNA polymerization. Since the Office does not have the facilities for examining and comparing applicants DNA with the prior art DNA, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594. The prior art anticipated the claimed invention.

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OS   Streptococcus pyogenes.
XX
PN   WO9842845-A1.
XX
PD   01-OCT-1998.
XX
PF   23-MAR-1998;   98WO-JP001288.
XX
PR   25-MAR-1997;   97JP-00071077.
XX
PA   (FUSO ) FUSO PHARM IND LTD.
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XX
PI   Ueyama H,  Abe K,  Keshi H,  Matsuhisa A;
XX
DR   WPI; 1998-532009/45.
XX
PT   New DNA probes, e.g. SP-6-28 or SP-7-44 - useful for, e.g. diagnosis of
PT   Streptococcus pyogenes infection.
XX
PS   Claim 2; Page 19-21; 48pp; Japanese.
XX
CC   AAV58284-V58289 are novel genomic DNA sequences which can be used as DNA
CC   probes for the diagnosis of Streptococcus pyogenes infection. These
CC   probes provide for simple and highly specific detection of S. pyogenes in
CC   biological samples such as blood
XX
SQ   Sequence 3200 BP; 1120 A; 547 C; 523 G; 1010 T; 0 U; 0 Other;

  Query Match             74.9%;  Score 849;  DB 2;  Length 3200;
  Best Local Similarity   98.7%;  Pred. No. 1.6e-171;
  Matches  866;  Conservative    0;  Mismatches   10;  Indels    1;  Gaps    1;

Qy          1 ATGATTCAATTTTCAATTAATCGCACATTATTTATTCATGCTTTAAATACAACTAAACGT 60
              ||||||||||||||||||||||||||||||||||||||||||||| ||||||||||
Db       2324 ATGATTCAATTTTCAATTAATCGCACATTATTTATTCATGCTTTAAATGCAACTAAACGT 2383

Qy         61 GCTATTAGCACTAAAAATGCCATTCCTATTCTTTCATCAATAAAAATTGAAGTCACTTCT 120
              |||||||||||||||||||||||||||||||||||||||||| ||||||||||||||||
Db       2384 GCTATTAGCACTAAAAATGCCATTCCTATTCTTTCATCAATAAAGATTGAAGTCACTTCT 2443

Qy        121 ACAGGAGTAACTTTAACAGGGTCTAACGGTCAAATATCAATTGAAAACACTATTCCTGTA 180
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       2444 ACAGGAGTAACTTTAACAGGGTCTAACGGTCAAATATCAATTGAAAACACTATTCCTGTA 2503

Qy        181 AGTAATGAAAATGCTGGTTTGCTAATTACCTCTCCAGGAGCTATTTTATTAGAAGCTAGT 240
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       2504 AGTAATGAAAATGCTGGTTTGCTAATTACCTCTCCAGGAGCTATTTTATTAGAAGCTAGT 2563

Qy        241 TTTTTTATTAATATTATTTCAAGTTTGCCAGATATTAGTATAAATGTTAAAGAAATTGAA 300
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       2564 TTTTTTATTAATATTATTTCAAGTTTGCCAGATATTAGTATAAATGTTAAAGAAATTGAA 2623

Qy        301 CAACACCAAGTTGTTTTAACCAGTGGTAAATCAGAGATTACCTTAAAAGGAAAAGATGTT 360
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       2624 CAACACCAAGTTGTTTTAACCAGTGGTAAATCAGAGATTACCTTAAAAGGAAAAGATGTT 2683

Qy        361 GACCAGTATCCTCGTCTACAAGAAGTATCAACAGAAAATCCTTTGATTTTAAAAACAAAA 420
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       2684 GACCAGTATCCTCGTCTACAAGAAGTATCAACAGAAAATCCTTTGATTTTAAAAACAAAA 2743

Qy        421 TTATTGAAGTCTATTATTGCTGAAACAGCTTTTGCAGCCAGTTTACAAGAAAGTCGTCCT 480
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       2744 TTATTGAAGTCTATTATTGCTGAAACAGCTTTTGCAGCCAGTTTACAAGAAAGTCGTCCT 2803

Qy        481 ATTTTAACAGGAGTTCATATTGTATTAAGTAATCATAAAGATTTTAAAGCAGTAGCGACT 540
              |||||||||||||||||||||||||||| ||||||||||||||||||||||||||||||
Db       2804 ATTTTAACAGGAGTTCATATTGTATTAAGCAATCATAAAGATTTTAAAGCAGTAGCGACT 2863

Qy        541 GACTCTCATCGTATGAGCCAACGTTTAATCACTTTGGAC-AATACTTCAGCAGATTTGAT 599
              |||||||||||||||||||||||||||||||||||| |||||||||||||||||
Db       2864 GACTCTCATCGTATGAGCCAACGTTTAATCACTTTGGACAAATACTTCAGCAGATTTTGA 2923

Qy        600 GGTAGTTCTTCCAAGTAAATCTTTGAGAGAATTTTCAGCAGTATTTACAGATGATATTGA 659
               || ||| ||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       2924 TGTGGTTATTCCAAGTAAATCTTTGAGAGAATTTTCAGCAGTATTTACAGATGATATTGA 2983

Qy        660 GACCGTTGAGGTATTTTTCTCACCAAGCCAAATCTTGTTCAGAAGTGAACACATTTCTTT 719
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       2984 GACCGTTGAGGTATTTTTCTCACCAAGCCAAATCTTGTTCAGAAGTGAACACATTTCTTT 3043
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Qy        720 TTATACACGCCTCTTAGAAGGAAATTATCCCGATACAGACCGTTTATTAATGACAGAATT 779
              ||||||||||||||||||||||||||||||||||||||| |||||||||||||||||||
Db       3044 TTATACACGCCTCTTAGAAGGAAATTATCCCGATACAGATCGTTTATTAATGACAGAATT 3103

Qy        780 TGAGACGGAGGTTGTTTTCAATACCCAATCCCTTCGCCACGCTATGGAACGTGCCTTCTT 839
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       3104 TGAGACGGAGGTTGTTTTCAATACCCAATCCCTTCGCCACGCTATGGAACGTGCCTTCTT 3163

Qy        840 GATTTCTAATGCTACTCAAAATGGTACTGTTAAGCTT 876
              |||||||||||||||||||||||||||||||||||||
Db       3164 GATTTCTAATGCTACTCAAAATGGTACTGTTAAGCTT 3200
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Remarks

12. Claims 1, 36, 55-57 and 94 are rejected.

Claims 37, 38 and 92-93 are allowed.

Conclusion

13. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The Right Fax number is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PMR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PMR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Jeffery Siew can be reached on (571) 272-0787. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Padma Baskar Ph.D.

SUSAN UNGAR, PH.D
PRIMARY EXAMINER